

Claims 1 and 14 have been amended to recite the transitional phrase "consisting essentially of" in place of comprising, thus leading to a more closed claim covering a more defined invention. Applicant respectfully submits that no new matter within the meaning of 35 U.S.C. §132 is added by the claim amendments.

Applicant thanks the Examiner for the indication that claims 15-18 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

The claim amendments are presented in the expectation that the amendments will place this application in condition for allowance. Accordingly, entry of the amendments is respectfully requested.

**1. REJECTION OF CLAIMS 1-14 AND 19-23**

**UNDER 35 U.S.C. §103(a)**

Claims 1-14, 19-23 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Fielden (U.S. Pat. No. 5,660,860) for the reasons set forth in the first Office Action.

**RESPONSE**

Applicant respectfully traverses this rejection. Applicant respectfully submits that the reference of record, Fielden, does not teach or suggest Applicant's inventive subject matter as a whole, as recited in the amended claims. Further, there is no

teaching or suggestion in this reference that would lead one of ordinary skill in the art to modify the reference to arrive at the subject of the amended claims with any expectation of success at the time the invention was made.

The U.S. Supreme Court in Graham v. John Deere Co., 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) inquiring as to any objective evidence of nonobviousness.

**A. The present inventive subject matter**

As amended, independent claim 1 is drawn to an encapsulated product, consisting essentially of: at least one active ingredient selected from the group consisting of: flavors, sweeteners, spices, herbal ingredients, vitamins, minerals, and mixtures thereof; at least one compressible material; and at least one lubricating material; wherein said product is in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters. Claims 3-13 are dependent therefrom adding further limitations.

Further, as amended, independent claim 14 is drawn to a method for preparing an encapsulated product consisting essentially of the

steps of: blending an active ingredient selected from the group consisting of: flavors, sweeteners, spices, herbal ingredients, vitamins, minerals, and mixtures thereof with a compressible material to form a compressible mixture; mixing said compressible mixture with a lubricating material to form a final mixture; and compressing said final mixture into a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters. Claims 15-18 and 20-23 are dependent therefrom adding further limitations.

**B. The prior art**

The Fielden patent (U.S. Pat. 5,660,860) discloses a water-dispersable tablet comprising acyclovir and a dispersing agent, with the main ingredient of the disclosure of Fielden being a swellable clay. The rejection cites the ingredients listed at col.9, lines 40-65 and col. 10, lines 25-34 as suggesting the claimed composition. Fielden discloses the ingredients acyclovir (5-90% wt); swellable clay (.25 to 50 % wt); binder (0-25 %wt); disintegrating agent (0-20 % wt); water-soluble filler (0-95% wt); water-insoluble filler (0-95% wt); wetting agent (0-5% wt); lubricant (0.1-5% wt); colours, flavours, sweeteners (0-10% wt); with an approximate tablet weight of 50-2000 mg.

**C. The differences between the claimed subject matter**  
**and the prior art**

As an initial "bookkeeping" matter, Applicant notes that the Examiner has maintained the rejection of claims 2 and 19, even though the claims have been canceled.

The differences between applicant's inventive subject matter and the cited reference is apparent from their independent and distinct disclosures and claim. Claims 1 and 14 are directed to an encapsulated product consisting essentially of at least one active ingredient selected from the group consisting of: flavors, sweeteners, spices, herbal ingredients, vitamins, minerals, and mixtures thereof at least one compressible material, and at least one lubricating material wherein the product is in the form of a caplet having a diameter and length of 1 to about 7 millimeters, and a method for making the same, respectively. It is well-known in U.S. patent law that the use of the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention. Applicant therefore respectfully submits that Fielden fails to teach or suggest an encapsulated product comprising the novel combinations of ingredients and sizes, as well as the method

of preparing the same. This is especially true given the unique nature of the combination of ingredients and sizes of the claimed product.

Applicant respectfully submits that Fielden is directed to a novel composition for the delivery of acyclovir to a patient, with an important aspect of Fielden being the **inclusion** of a **swellable clay** such as smectite or bentonite. A careful review of Fielden reveals that the examples and claims in Fielden include acyclovir and a swellable clay, as **there is no disclosure for preparing an encapsulated product consisting essentially of the components claimed in amended claims 1 and 14 of the present application.** The modestly few components that are listed in Fielden are used to supplement **the acyclovir and swellable clay** that are an essential part of Fielden. The disclosure of Fielden makes it clear that the additional components are **not important** to the compositions containing acyclovir and the swellable clay.

Further, Applicant respectfully submits that there is also no suggestion, teaching or motivation within the reference to **not** include acyclovir or a swellable clay. And as is further stated above, it is **very important** to the Fielden disclosure to include the swellable clay for dispersal properties in the tablets. In fact, the whole objective of the Fielden reference is to improve the dispersion characteristics of the tablet by using **the swellable**

**clay.** Thus, there is no motivation or suggestion to prepare compositions that are absent the swellable clay.

To reiterate the above statements, the present inventive subject matter, on the other hand, is directed to an encapsulated product in which the active ingredient is selected from the group consisting of: flavors, sweeteners, spices, herbal ingredients, vitamins, minerals, and mixtures thereof. In addition, as is claimed in claims 9 and 20, the compressible material used in the inventive products of the present application include, without limitation, sugar, polyols, mineral salts, dextrose, sorbitol, isomalt, maltitol, xylitol, lactitol, calcium phosphate, and mixtures thereof. **By the claim amendments included herein, Applicant is clearly not contemplative of swellable clays being included in the presently claimed inventive subject matter, and thus the present claims are very distinct over the Fielden reference.**

Based on the independent and distinct disclosures of the present application and the Fielden reference, Applicant respectfully submits that independent claims 1 and 14 are not taught or suggested by Fielden, thus, a prima facie case of obviousness has not been established. Dependent claims 3-8 and 10-13, and 15-18 and 20-23, which incorporate all the limitations of claims 1 and 14, respectively, therefore, must also be patentable

over Fielden.

Applicant respectfully requests reconsideration and withdrawal of the 35 USC § 103 rejections of claims 1-14 and 19-23.

**2. REJECTION OF CLAIM 24 UNDER 35 USC § 103(a)**

The Office Action rejects claim 24 under 35 USC § 103(a) as allegedly being unpatentable over Cherukuri et al. (4,981,698) for the reasons set forth in the Office Action.

**RESPONSE**

Applicant respectfully traverses this rejection. Applicant respectfully submits that the reference of record, Cherukuri et al. does not teach or suggest the subject matter as a whole of independent claim 24 as recited in the claims. Further, there is no teaching or suggestion in this reference which would lead one of ordinary skill in the art to modify the reference to derive the subject matter as defined in claim 24.

The four-pronged test of Graham v. John Deere, is discussed above.

**A. The present inventive subject matter**

As amended herein, claim 24 is presently directed to a method of delivering two flavor ingredients to an item selected from the

group consisting of: a food item, a confectionery product, and a chewing gum product, said method comprising the steps of: incorporating into said item a first encapsulated product containing a first flavor; and incorporating into said item a second encapsulated product containing a second flavor; wherein said first and said second encapsulated products each have a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters.

**B. The prior art**

Cherukuri et al. discloses a delivery system for one or more sweeteners comprising a first high intensity sweetener encapsulated in a first core coating, and a second outer hydrophillic coating containing up to the solubility limit of the second coating of a second sweetener in the same product. In other words, Cherukuri et al. disclose a product that contains two sweeteners encapsulated in **coatings of the same product.**

**C. The differences between the claimed subject matter  
and the prior art**

The first Office Action cites the abstract and col. 20, lines 29-32 which are steps (b) and (c) of claim 27 of Cherukuri et al. as rendering claim 24 obvious. However, the cited reference fails to teach or suggest a method of delivering **two flavor ingredients**

①



to a food item by **separately** encapsulating a first flavor which is incorporated into the food item and then separately delivering a second encapsulated flavor into the food item, with both flavors being encapsulated **in separate products prior to being introduced into the food item**. Further, the encapsulated products containing the flavors being introduced into the food item **each have a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters**. Applicant respectfully submits that Cherukuri is silent as to the requirement of the encapsulated products containing the flavors have the structural limitations as set forth in amended claim 24 (i.e., that the encapsulated products have a size of 1-7 mm in diameter and 1-7 mm in length).

On the other hand, Cherukuri et al. utilizes a distinct method by which a structurally distinct product in the form of a sweetener is introduced into the **coating** of the same product. In Cherukuri et al., a first sweetener is encapsulated in a first core **coating** with the resultant product being encapsulated with a **second hydrophillic coating** containing up to the solubility limit of the second coating of the second sweetener. The important aspect of Cherukuri et al. is the fact that the sweeteners are incorporated **into the same product via the coatings** prior to being added to a

0

gum or food item. Therefore, Applicant respectfully submits that Cherukuri et al. is irrelevant to claim 24 since claim 24 requires two encapsulated flavors **with important structural limitations** to be introduced into the food item. The encapsulations are separate from each other in claim 24, as is evidenced by the requirement that two encapsulated products containing different flavors be introduced into the food item.

Likewise, there is no motivation or teaching in Cherukuri et al. to modify it in an attempt to achieve the present inventive subject matter. Cherukuri et al. are concerned with encapsulating two sweeteners into a product **via coating**, whereas the present claims are not concerned with coatings. Thus, there is no reason to modify the coating process of Cherukuri et al. to attempt achieving the present invention.

Thus, there is no teaching or suggestion of the inventive subject matter of claim 24 nor any suggestion to modify the teachings of Cherukuri et al. to arrive at claim 24. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 24 as being obvious over Cherukuri et al.

#### **CONCLUSION**

In view of the foregoing, Applicant respectfully submits that the present claims are patentable over the prior art of record in

Attorney Docket No. 24222  
Serial No. 09/587,971

this case and requests the Examiner to reconsider and withdraw the rejection of the claims and to allow all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

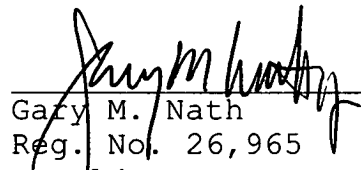
Respectfully submitted,

**NATH & ASSOCIATES**

Date: September 17, 2002

**NATH & ASSOCIATES**

1030 Fifteenth Street, N.W.  
Sixth Floor  
Washington, D.C. 20005  
Tel: (202) 775-8383  
Fax: (202) 775-8396  
GMN:JLM:jkh:24222.roal.wpd

  
\_\_\_\_\_  
Gary M. Nath  
Reg. No. 26,965  
Jerald L. Meyer  
Reg. No. 41,194